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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/161,122	09/25/1998	HONG JIN	7682-45	7220
20583	7590	11/16/2004	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			LUCAS, ZACHARIAH	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/161,122

Applicant(s)

JIN ET AL.

Examiner

Zachariah Lucas

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 19-28 is/are pending in the application.
- 4a) Of the above claim(s) 1,3-12,14-17 and 19-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,13 and 25-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6-17-04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1648

DETAILED ACTION

Status of the Application

1. In this application, claims 1-17, and 19-28 are pending. Claims 2, 13, 25-28 are under consideration. Claims 1, 3-12, 14-17, and 19-24 have been withdrawn from consideration as to non-elected inventions.
2. In the prior office action, mailed April 20, 2004, claims 2, 13, and 25-28 were rejected. In the Response filed on September 17, 2004, the Applicant amended the specification, and amended claims 13, and 26-28.

Specification

3. In the prior action, the specification was objected because the specification was claiming priority to an application with which the present application does not share the same disclosure (Application 60/084,153). In view of the deletion of the amendment of application such that it no longer claims priority to this application, the objection is withdrawn.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on June 17, 2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Double Patenting

Art Unit: 1648

5. **(Prior Rejection- Maintained)** Claims 2, 13, 18, and 25 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6 and 7 of U.S. Patent No. 5,840,520. It noted that claim 27 was inadvertently left out of this rejection although it is drawn to substantially the same subject matter as claim 25. This claim is included in the rejection, and is not considered to raise a new ground of rejection. The Applicant continues to traverse the rejection on the grounds that "the disclosure or the patent underlying the double patent rejection may not be used as prior art against the claims under consideration." In support of the traversal, the Applicant points out the statement in MPEP § 804 that "When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art"; and then cites the Federal Circuit case of *In re Kaplan* (229 U.S.P.Q. 678, 1986). These arguments are not found persuasive. The rejection is therefore maintained against claims 2, 13, 18, 25, and 27.

With respect to the citation to MPEP § 804, it is noted that the sentence reproduced by the Applicant is not the whole of what the MPEP says on the matter. As was noted in the prior action, the very next sentence of the MPEP states, "This does not mean that one is precluded from all use of the patent disclosure." The court in *Vogel* recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. 164 U.S.P.Q. 619, 622. The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C.

Art Unit: 1648

103, since only the disclosure of the invention claimed in the patent may be examined." *Id.* Thus, the courts have held that it is permissible to use the specification in determining what is included in, and obvious from, the invention defined by the claim on which the rejection is based. This is true even where elements are drawn from the specification describing the claimed invention, which are not elements in the claim itself. The Applicant's first argument in traversal is therefore not found persuasive.

The second argument in traversal is that the Federal Circuit held, in *In re Kaplan*, that obviousness double patenting did not apply in a factual situation much like that of the present case. Thus, the Applicant's citation to *In re Kaplan* appears, at first glance, to be determinative of the issue. However, this is not the end of the story. As can be seen in the court's decision, the Federal Circuit panel deciding the case spent a significant portion of the background section discussing the relative inventorship of the application, and claims being rejected in the application, as compared to the inventors of the patent claims. 229 U.S.P.Q. at 679-80. This is because the law under which the case was decided required that all the inventors named in the application contributed to all claimed inventions. Thus, because the rejected claims in the application had different inventorship from the claims in the patent, the claims of the application could not have been claimed in the patent. See, MPEP II.B.2. This law was changed in 1984 so that all named inventors need not contribute to each claimed invention. Thus, the decision of *Kaplan* no longer applies.

For the reasons above, and the reasons of record, the Applicant's arguments in traverse are not found persuasive. The rejection is therefore maintained.

Art Unit: 1648

6. **(Prior Rejection- Maintained)** Claims 2, 13, 18, and 25 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25, 26, 27, and 32 of copending application 09/923,070. Because the rejection is provisional, the Applicant's have not addressed the rejection. It is therefore maintained.

7. **(Prior Rejection- Maintained)** Claim 2 was rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over either claims 1 and 12 of U.S. Patent No. 5,820,871, or claims 1 and 16 of U.S. Patent No. 5,166,057, in view of Klein et al. (U.S. Patent 6,033,668) and the teachings of any of Beeler et al. (J Virol 63:2941-50 -of record in the March 2000 IDS), Mufson et al. (J Gen Virol 66: 211-24 (1985), or Sullender et al. (Virology 178(1): 195-203). The Applicant traverses this rejection on the grounds that the teachings in the specifications of the prior patents may not be used as prior for the reasons indicated with respect to the rejection over U.S. Patent 5,840,520 above, and that absent these teachings, the other cited references do not teach the currently claimed invention. This argument is not found persuasive for the reasons described above. Because the teachings of the 871 and 057 patents, insofar as they describe the inventions claimed in those patents, may be used in making an obviousness type double patenting rejection, the Applicant's arguments are not found persuasive and the rejection is maintained.

8. **(New Rejection- Necessitated by Amendment)** Claims 26 and 28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6 and 7 of U.S. Patent No. 5,840,520 as applied above in view of Murphy et al., U.S.

Art Unit: 1648

Patent 5,993,824. These claims have been amended to read on the chimeric viruses of claims 2 and 13 respectively, wherein the virus also contains a deletion of either of the RNA regions M2-ORF 2 or the SH-ORF of the RSV genome. It is noted that these embodiments are not supported by the description in the 08/316,439 application.

The teachings of the 520 patent have been described in the prior actions. While the patent teaches that the “heterologous sequence” of the chimeric RSV can comprise “additions and/or deletions in the nucleotide sequence and/or gross alterations in the genetic structure of native RSV,” the reference does not specifically suggest deletion of either of the indicated genomic regions. However, Murphy teaches the modification of an RSV through deletion of the SH gene in order to achieve “enhanced growth in vitro and/or attenuation in vivo.” Column 6, lines 20-26. The reference additionally teaches that other genes, including M2 ORF2, may be deleted to make RSV with desired characteristics. Column 6, lines 1-20. See also, Collins et al., PNAS 93: 81-85 and Hardy et al., J Virol 72:520-26. From the teachings in the art, those in the art would have had a reasonable expectation of success in the making of a recombinant RSV virus comprising a deletion of M2-ORF2. Thus, the embodiments of claims 26 and 28 are obvious variants of the chimeric RSV of claims 6 and 7 of the 520 patent.

Claim Rejections - 35 USC § 112

9. **(Prior Rejection- Withdrawn)** Claims 26 and 28 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it was not clear what is meant by the “SH-ORF2.” In view of the amendment of the claims to remove reference to this ORF, the rejection is withdrawn.

Art Unit: 1648

10. **(Prior Rejection- Withdrawn)** Claims 2, 13, 18, 25, and 26 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. In view of the Applicant's argument in traversal of the rejection, the rejection is withdrawn.

11. **(Prior Rejection- Withdrawn)** Claims 13, 27, and 28 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions comprising a chimeric RSV, does not reasonably provide enablement for vaccines comprising such a virus. In view of the amendment of the claims such that they now read on immunogenic compositions, rather than vaccines, the rejection is withdrawn.

12. **(Prior Rejection- Withdrawn)** Claims 26 and 28 were rejected under 35 U.S.C. 112, first paragraph, as failing to provide adequate written description for RSV particles wherein the RNA comprises a deletion of SH-ORF2. In view of the amendment of the claims such that they no longer refer to the deletion of the SH- ORF2, but read on the deletion of the SH-ORF, the rejection is withdrawn.

Conclusion

13. No claims are allowed.

14. The following prior art reference is made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

U.S. Patent 6,689,367. Although not considered prior art to the pending claims, the claims of this patent are drawn to similar subject matter. See e.g., Claims 1, 6, 7, 38, and 42.

Art Unit: 1648

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

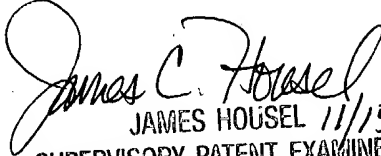
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner


JAMES HOUSEL 11/15/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600